

**Amendment and Response**

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Serial No.: 10/028,041

Confirmation No.: 3159

Filed: 21 December 2001

For: SELF-VENTING MOVABLE SEAL AND PLUNGER

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**Remarks**

The Office Action mailed 12 February 2004 has been received and reviewed. The pending claims are claims 1-23, with claims 1-14, 17, and 20-23 having been withdrawn from consideration. Thus, claims 15, 16, 18 and 19 are pending and currently under examination.

Reconsideration and withdrawal of the rejections in view of the following comments are respectfully requested.

**Drawings**

The Examiner objected to the drawings as failing to comply with 37 C.F.R. §1.84(p)(5) as including reference signs 18a, 18b, and 32 not mentioned in the description, and including reference sign 18 not mentioned in the drawings.

In response thereto, Applicants herewith submit proposed corrections to the drawings that remove reference signs 18a, 18b, 32, 114, 116, 118a, 118b, 128, 134, 218a, 218b, and 318b from the drawings. The proposed corrections also introduce reference sign 18 in Figure 1A, reference sign 218 in Figures 3A and 3B, and reference sign 318 in Figure 4. Further, additional corrections to the drawings are proposed herein to remove reference signs not mentioned in the description and add reference signs mentioned in the description but inadvertently omitted from the drawings. Applicants submit that these are merely typographical errors and no new matter has been added as a result of the proposed corrections.

Approval of the proposed corrections, along with reconsideration and withdrawal of the objection to the drawings, are respectfully requested.

**The Restriction Requirement and Species Election**

In response to the Restriction Requirement mailed November 11, 2003, Applicants elected, with traverse, to pursue the claims of Group III (claims 15-23) drawn to a device.

The Restriction Requirement further requested that Applicants select a species, drawn to either Figs. 1a-c and 3a-b (I; claims 15, 16, 18, and 19) or to Fig. 2 (II; claims 17 and 20-23). Applicants made no species election; thus in the present Office Action the Examiner selected species I, drawn to claims 15, 16, 18, and 19. Applicants respectfully traverse this restriction.

It is stated in the Restriction Requirement that upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141.

Applicants respectfully point out that all the limitations of independent claim 15 (species I) are also present in independent claim 20 (species II). Thus, it is asserted that claim 15 is generic to claim 20. Applicants request, therefore, that claims 17 and 20-23 of species II be rejoined with species I upon the allowance of generic claim 15.

#### **The 35 U.S.C. §102 Rejection**

The Examiner rejected claims 15-16 and 18-19 under 35 U.S.C. §102(b) as being anticipated by Etherington (U.S. Patent No. 4,660,569).

The Examiner rejected claims 15-16 under 35 U.S.C. §102(b) as being anticipated by Bailey (U.S. Patent No. 4,257,426).

The Examiner rejected claims 15-16 under 35 U.S.C. §102(b) as being anticipated by Schwartz (U.S. Patent No. 3,566,859).

The Examiner rejected claims 15-16 under 35 U.S.C. §102(b) as being anticipated by Marzolf et al. (U.S. Patent No. 4,615,341).

Applicants respectfully traverse these rejections.

For a claim to be anticipated under 35 U.S.C. § 102(b), each and every element of

the claim must be found in a single prior art reference (M.P.E.P. §2131). Applicants respectfully assert that each of the cited documents fail to teach each and every element of the rejected claims.

Claim 15 recites, *inter alia*, a self-venting movable seal and plunger assembly that includes a hollow cylindrical body and a movable seal that further includes a plunger tip pocket, a vent extending between the plunger tip pocket and the second end of the movable seal, wherein the plunger tip pocket is in fluid communication with the volume within the hollow cylindrical body when the movable seal is located within the hollow cylindrical body. Claim 15 further includes a plunger tip that includes at least one vent channel, wherein the plunger tip is configured to seat within the plunger tip pocket of the movable seal, wherein the plunger tip occludes the vent in the movable seal when the plunger tip is seated within the plunger tip pocket, and further wherein fluid within the plunger tip pocket escapes through the at least one vent channel in the plunger tip as the plunger tip is seated in the plunger tip pocket.

Etherington (U.S. Pat. No. 4,660,569)

Etherington fails to teach each and every element of claims 15-16 and 18-19 as required for a proper anticipation rejection.

Although it is asserted that Etherington includes a plunger pocket tip (which Applicants assume to mean a plunger tip pocket) and a plunger tip, the Office Action does not indicate which structures of Etherington are considered the plunger tip pocket and plunger tip. If this rejection is to be maintained, Applicants respectfully request some identification as to which structures of Etherington are considered to constitute the plunger tip and the plunger tip pocket.

Furthermore, the assertions made in support of this rejection are not supported by the reference itself. For example, it is asserted that “when the plunger is not yet fully seated in the movable seal the vent opening in the movable seal is occluded due to resiliency of the seal material.” Applicants respectfully traverse this assertion for at least two reasons.

First, Etherington teaches that a gas permeable plug 32 is located within barrel stem 23a to allow gas (air) to pass through channel 33 during movement if sealing means 15. As a result, Etherington does not teach an assembly in which "the plunger tip occludes the vent in the movable seal when the plunger tip is seated within the plunger tip pocket" as recited in independent claim 15. Rather, the gas permeable plug 32 allows venting even when the barrel stem 24A is seated in the sealing means 15.

Second, the assertions made in support of this rejection are not supported by the teachings of Etherington. If it is the Examiner's intent to rely on inherent characteristics of the Etherington disclosure, then Applicants submit that the requirements for a proper § 102 rejection based on inherent characteristics of the structures of Etherington have not been met. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *MPEP* § 2112, p. 2100-52, 8<sup>th</sup> Ed., Rev. 1, (Feb. 2003) (emphasis in original). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

There is, however, no discussion in the Office Action regarding why or how the structures of Etherington meet the limitations recited in claim 15, as well as claims 16, 18, and 19 dependent thereto. The rejection is, instead, based on unsupported assertions.

For example, with respect to the rejection of claim 15, there is no indication as to which structures are considered the plunger tip and the plunger tip pocket, much less any indication whatsoever of a plunger tip configured to seat within the plunger tip pocket of the movable seal. Additionally, while there is a plug 32 of air permeable, liquid impermeable material within the barrel stem, there is no teaching either (1) that it is configured to be seated within the plunger tip pocket of the movable seal, (2) that it occludes the vent in the movable seal when seated in the plunger tip pocket of the movable seal, or (3) that it includes at least one vent

channel wherein fluid within the plunger tip pocket escapes through the at least one vent channel in the plunger tip when the plunger tip is seated in the plunger tip pocket. Furthermore, no discussion is provided to show that any of the claimed features necessarily flow from the structures of Etherington.

In addition, the Office Action fails to identify structure disclosed in Etherington that occludes the vent in the movable seal when the plunger tip is seated within the plunger tip pocket. The barrel stem “can be closed off at the exit opening 34 by selectively using a plug 35 . . . or by the placement of a finger” (Etherington, col. 4, lines 19-22); however, such a plug or finger is not a plunger tip, nor is it seated in a plunger tip pocket as recited in the rejected claims. Further, the Office Action fails to show how the features of the rejected claims, such as providing a plunger tip that occludes the vent in the movable seal when the plunger tip is seated within the plunger tip pocket, necessarily flow from the teachings of Etherington. Thus the requirements for anticipation based on inherency have not been met with respect to claims 15, 16, 18, and 19.

For at least the foregoing reasons, Applicants assert that Etherington fails to teach all elements of independent claim 15. Applicants further assert that claim 15, as well as claims 16, 18, and 19 dependent thereto are novel in view of Etherington.

Bailey (U.S. Pat. No. 4,257,426)

Bailey also fails to disclose each and every feature of rejected claims 15-16 as required for a proper anticipation rejection.

The Office Action identifies, in the structures of Bailey, “a hollow cylindrical body, a movable seal 28 comprising a plunger pocket tip 29 a vent 32, and a plunger tip comprising at least one vent channel.” (Office Action, page 4, paragraph 4).

Reference sign 29 of Bailey refers to a recess in which the tubular plunger body 31 is received (Bailey, col. 3, lines 28-30). There is no teaching that the tubular plunger body 31 “occludes the vent in the movable seal when the plunger tip is seated within the plunger tip

pocket” as recited in claim 15. In fact, the hollow tubular body 31 provides a continuation of lateral vent 32 to ambient atmosphere. “The lateral vent 32, and the hollow plunger body 31, define a fluid passageway between the leading end void space 42 and the ambient environment (Fig. 5).” (Bailey, col. 4, lines 23-25). Any assertion that the tubular body 31 seals a vent in the movable seal of Bailey is not supported by the teachings of the reference itself.

For at least the foregoing reasons, Applicants assert that Bailey fails to teach all elements of independent claim 15. Applicants further assert that claim 15, as well as claim 16 dependent thereto, are novel in view of Bailey.

Schwartz (U.S. Pat. No. 3,566,859)

Schwartz also fails to disclose each and every feature of claims 15-16 as required for a proper anticipation rejection.

It is asserted in the Office Action that “Schwartz discloses a self venting seal and plunger system comprising a hollow cylindrical body 20, a movable seal comprising a plunger pocket tip, a vent 34, and a plunger tip comprising at least one vent channel.” (Office Action, page 4, paragraph 6).

The Office Action provides no discussion as to how, in the Schwartz devices, the plunger tip occludes a vent in the movable seal when the plunger tip is seated within the plunger tip pocket. In fact, as Figure 2 of Schwartz shows the intermixing of the two separate components shown in the syringe of Figure 1 (Schwartz, col. 2, lines 21-25), it flows from the teachings of Schwartz that the plunger tip cannot occlude the vent in the movable seal when the plunger tip is seated in the within the plunger tip pocket. Occlusion of the vent 34 would prevent mixing of the two components as depicted in Fig. 2 of Schwartz. Thus, not only does Schwartz fail to teach all elements of claims 15 and 16, inherently or otherwise, it teaches away from claims 15 and 16.

For at least these reasons it is asserted that Schwartz fails to teach all elements of claim 15 and claim 16 dependent thereto; thus, reconsideration and withdrawal of the rejection is respectfully requested.

Marzolf et al. (U.S. Pat. No. 4,615,341)

Marzolf et al. also fail to disclose each and every feature of rejected claims 15 and 16 as required for a proper anticipation rejection.

It is asserted in the Office Action that Marzolf et al. “disclose a self venting seal and plunger system comprising a hollow cylindrical body 12, a movable seal 32 comprising a plunger pocket tip, a vent 60, and a plunger tip comprising at least one vent channel 56.” (Office Action, page 5, paragraph 1).

Figures 1-3 of Marzolf et al. disclose a fluid sampling device including a housing 12 and a piston member 32 that acts as a sealing member. The piston member 32 includes a cavity 36 that receives an end portion or mounting member 50 of plunger 26 (Marzolf et al., col. 5, lines 7 and 28-33). The plunger and mounting member include holes 56 and channels 58 and the piston member 32 includes ports 60 such that chamber 34 is in fluid communication with cavity 30 and gases may pass through port 60, through channels 58, and through holes 56 into cavity 30 (Marzolf et al., col. 6, lines 14-31 and Figures 2-5). The holes and channels, 56 and 58, that align with ports 60 in the piston member when the mounting member is seated in the cavity of the piston member provide an exhaust passageway for venting contaminant gases from chamber 34. When the sample is being drawn (i.e., the mounting member is seated in the piston member), fluids in the form of gaseous contaminants are evacuated through the passageways (Marzolf et al., col. 3, lines 9-11).

Thus, not only does Marzolf et al. fail to teach a plunger tip configured to seat within the plunger tip pocket of the movable seal, wherein the plunger tip occludes the vent in the movable seal when the plunger tip is seated within the plunger tip pocket (as recited in claim 15), Marzolf et al. teach away from occlusion of vents 56 and 58 because, if the vent 60 were

occluded when the plunger tip is seated within the plunger tip pocket, the gaseous contaminants could not be evacuated through the passageways. Occlusion of vents 56 and 58 (and, therefore, port 60) is instead achieved by swelling of a fiber. See, e.g., Marzolf et al., col. 3, lines 50-57.

For at least the foregoing reasons, Applicants assert that Marzolf et al. fail to teach all elements of independent claim 15. Applicants further assert that claim 15, as well as claim 16 dependent thereto, are novel in view of Marzolf et al.

For at least the above reasons, Applicants assert that none of the cited documents teach each and every aspect of the rejected claims. Reconsideration and withdrawal of the rejections are, therefore, respectfully requested.



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**Summary**

It is respectfully submitted that the pending claims 15, 16, 18, and 19, currently under consideration, are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
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**CERTIFICATE UNDER 37 CFR §1.10:**

"Express Mail" mailing label number: EV 405 459 678 US      Date of Deposit: 14 June 2004

The undersigned hereby certifies that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Name: Sandy Truehart  
By: Sandy Truehart

Signature: \_\_\_\_\_

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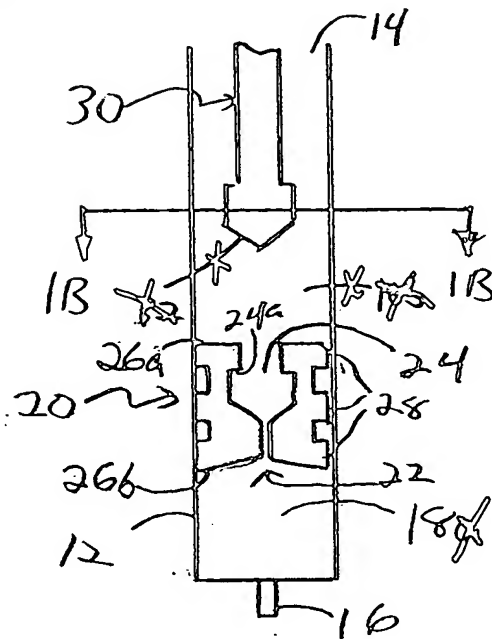


Figure 1A

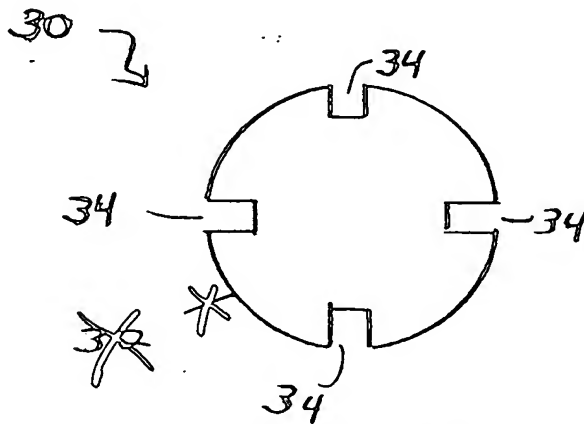


Figure 1B

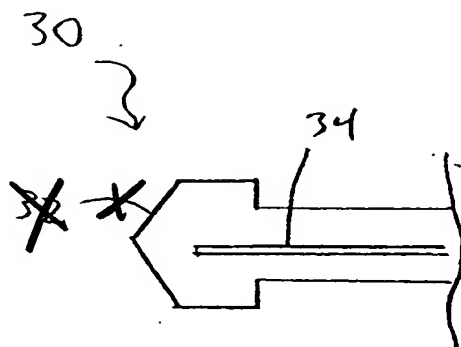


Figure 7C

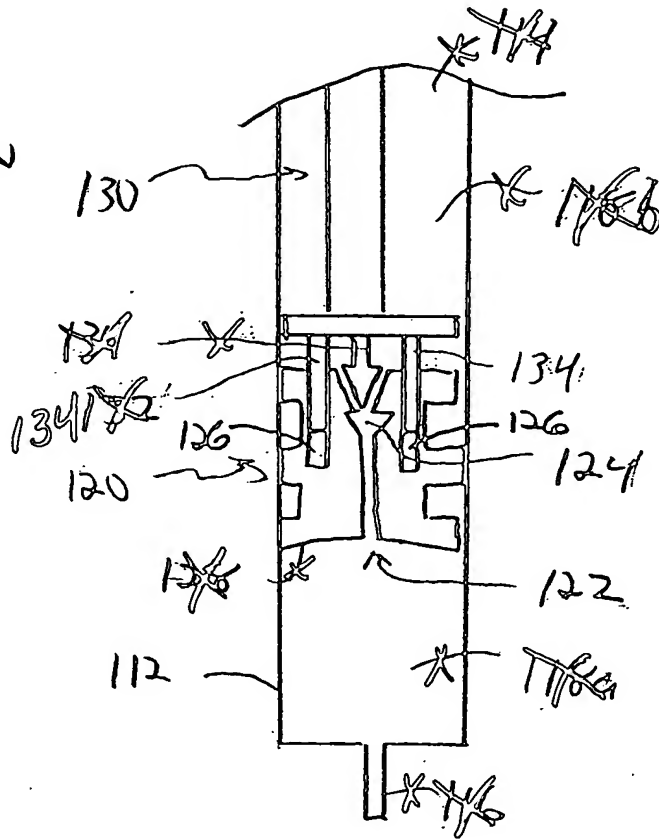
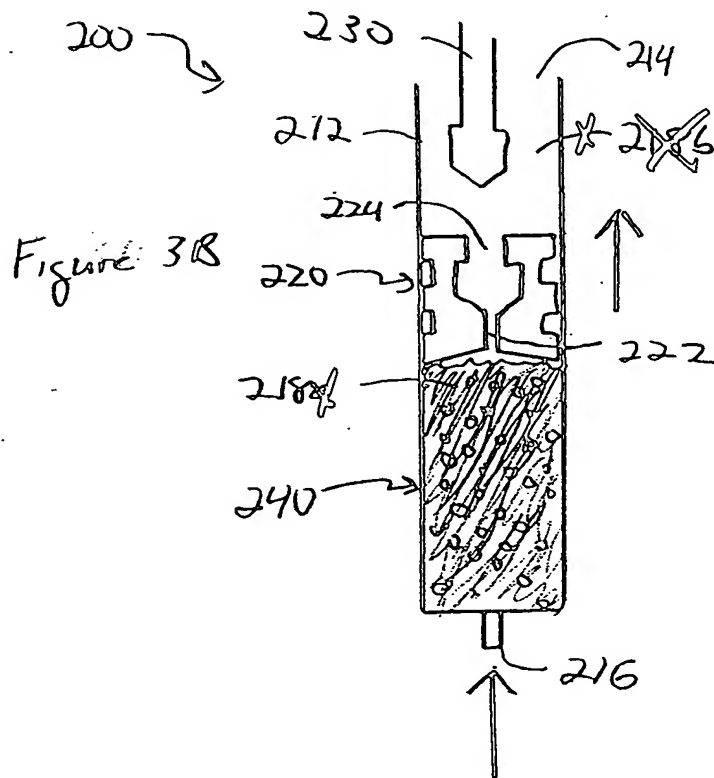
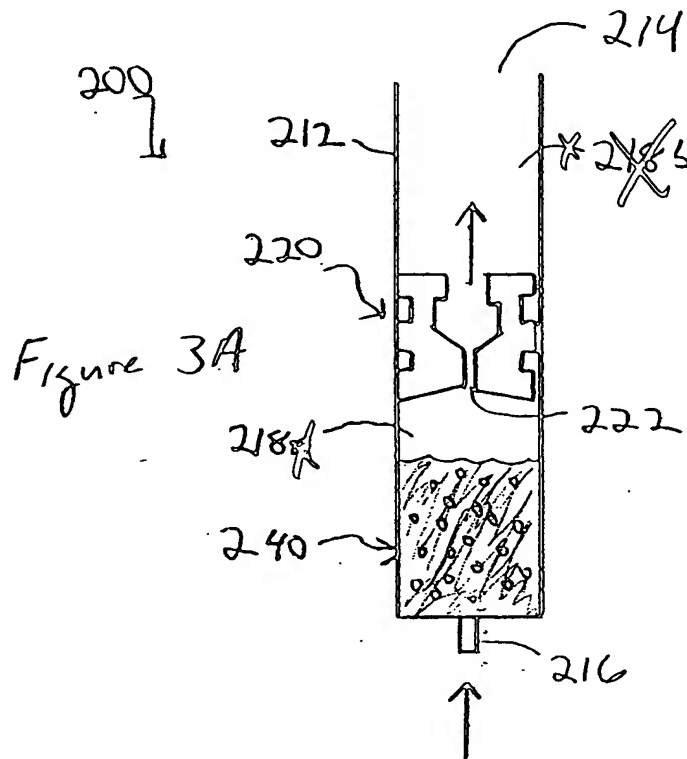


Figure 2



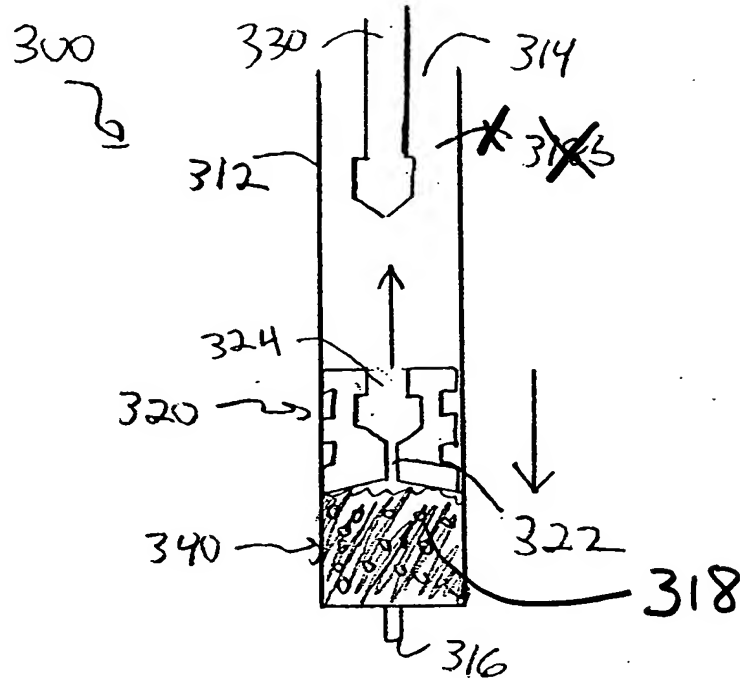


Figure 4